

117TH CONGRESS
2D SESSION

H. R. 7192

To provide for the establishment of a panel on the real world impact of diagnostic medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 21, 2022

Ms. SCHRIER introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for the establishment of a panel on the real world impact of diagnostic medical devices, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Diagnostic Device Ad-
5 visory Committee Act”.

6 **SEC. 2. REAL WORLD IMPACT OF MEDICAL DEVICES PANEL.**

7 (a) IN GENERAL.—The Secretary of Health and
8 Human Services (in this section referred to as the “Sec-
9 retary”) shall, without regard to the provisions of title 5,
10 United States Code, governing appointments in the com-

1 petitive service, and without regard to the provisions of
2 chapter 51 and subchapter III of chapter 53 of such title
3 relating to classification and General Schedule pay rates,
4 amend the charter of the Medical Devices Advisory Com-
5 mittee (or successor advisory committee) to establish a
6 panel of experts on diagnostic medical device products for
7 the purpose of providing advice to the Secretary in connec-
8 tion with the real world impact of the clearance, classifica-
9 tion, approval, and authorization of devices, including di-
10 agnostic devices, under sections 510(k), 513(f), 515, and
11 564 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 360(k), 360c(f), 360e, and 360bbb–3) to be known
13 as the Real World Impact of Medical Devices Panel (re-
14 ferred to in this section as the “Panel”).

15 (b) APPLICATION OF FACA.—The Federal Advisory
16 Committee Act shall apply to the Panel.

17 (c) MEMBERSHIP.—

18 (1) IN GENERAL.—The Panel shall consist of
19 15 members, including the Chair.

20 (2) REPRESENTATION.—11 members of the
21 Panel shall be voting members. Of the remaining 4
22 members of the Panel—

23 (A) 1 shall be a representative of consumer
24 interests;

12 (d) DUTIES.—The Panel shall provide to the Sec-
13 retary—

22 (2) register comments about the negative and
23 positive impacts of such devices on the United
24 States population, the risk assessment posed by the

1 use of such devices, and the need such devices would
2 fill.

3 (e) CONSIDERATION OF RECOMMENDATIONS.—The
4 Secretary, acting through the Commissioner of Food and
5 Drugs, and any other applicable official shall, in making
6 any final decisions, or amending existing decisions with
7 respect to the clearance, classification, approval, and au-
8 thorization of devices, including diagnostic devices, under
9 sections 510(k), 513(f), 515, and 564 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 360(k),
11 360c(f), 360e, and 360bbb-3), take comments received
12 from the Panel under advisement.

13 (f) MEETINGS.—

14 (1) FREQUENCY.—The Panel shall hold at least
15 1 meeting each year, at the call of the Chair.

16 (2) RECORDINGS AVAILABLE.—Recordings of
17 the meetings of the Panel shall be available on the
18 public website of the Food and Drug Administration.

